MINUTES FROM THE EPA/SCIENCE ADVISORY BOARD
Drinking Water Committee Meeting
June 5-7, 2000

Purpose of the Meeting:

The Drinking Water Committee (DWC) of the U.S. Environmental Protection Agency's (EPA) Science Advisory Board (SAB) met in Washington, D.C. from June 5 through 7, 2000 to confer on a number of issues relevant to the EPA drinking water program (elements of the proposed Arsenic Drinking Water Standard and consideration of possible DWC - EPA interactions on Stage 2 of the Microbial/Disinfection Byproducts rule making-- M/DBP2). Days one and two of the meeting were held in the Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW, Washington, D.C. and for day three, panelists met at the US EPA Headquarters building (Ariel Rios North, Room 6013, 1200 Pennsylvania Avenue, NW). The meeting was announced in the *Federal Register* (Vol. 65, No. 93, Page 30589-30590, May 12, 2000–see Attachment A). An agenda for the meeting is contained in Attachment B, and a roster of panelists is found in Attachment C.

SUMMARY OF THE MEETING:

A. Monday, June 5, 2000

1. Convening the Meeting and Introductions, Dr. Richard Bull, Chairman

Dr. Richard Bull, Chairman of the DWC, called the meeting to order at 9:05 am. He welcomed members of the panel, EPA, and the public. He noted the issue before the DWC for the meeting, the charge, and that not much technical information had been provided by EPA for the review. He also noted his desire to complete the DWC's efforts and to draft portions of the report to the Administrator on day 3 of this meeting. He noted the arsenic discussions and papers that were a part of the recently concluded annual meeting of the Society of Toxicology.

Dr. Bull then asked the members and consultants constituting the Arsenic Review Panel to introduce themselves and to engage in the Board's voluntary disclosure process (see Attachment D). Mr. Miller, DFO for the DWC explained the purpose of the disclosure process. Panelists then engaged in this process. In attendance were the following members of the DWC: Drs. Richard Bull, David Baker, Mary Davis, Ricardo DeLeon, Yvonne Dragan, John Evans, Barbara Harper, L.D. McMullen, Charles O'Melia, and Gary Toranzos. Consultants assembled to assist the committee in the arsenic review included: Drs. Michael DeBaun (days 1 and 2 only), Janet Hering, Issam Najm, John Rosen (days 1 and 2 only), and Louise Ryan (day 2 only). Mr. Thomas Miller was the Designated Federal Officer and Ms. Dorothy Clark was the Management Assistant.

Though no panelist had a Conflict of Interest, a number of panelists indicated for the record, past interactions that they believed the public should be aware of so they could judge for themselves the independence of their comments. The following items were noted: 1) Dr. Dragan has conducted some research on the carcinogenic potential of arsenic in animals; 2) Dr. Evans noted he has received EPA grant funds but that these were not related to arsenic and that he was on the Doctoral Committee for an

author of one of the papers cited in EPA's arsenic background documentation -- MacIntosh; 3) Dr. Harper noted her work on arsenic in the food chain; 4) Dr. De Leon noted receipt of EPA grant funds in the past and work on arsenic removal by his employer, the Metropolitan Water District; 5) Dr. O'Melia noted receipt of EPA grant funds and work on coagulation; 6) Dr. Hering noted a considerable amount of research on arsenic for EPA, the American Water Works Association Research Foundation, and the Los Angeles Department of Water and Power; 7) Dr. Najm noted that his employer has done some applied arsenic research and his work on treatment processes - not arsenic; 8) Dr. McMullen noted his association with the Des Moines Water Works, the National Drinking Water Advisory Council, a Freedom of Information Act request to EPA, and the receipt of EPA grant funds; 9) Dr. Davis noted past receipt of EPA grant funds; 10) Dr. DeBaun noted only his work as an expert witness on acute arsenic poisonings and his epidemiology work; and 11) Dr. Rosen noted his technical assistance work at Superfund sites, work on lead, work with the Navaho tribes on multiple toxicants, and his pediatric practice. Dr. Bull then asked the public and Agency representatives to identify themselves. Persons present are shown on the sign-in sheets attached to these minutes – Attachment E.

2. <u>Opening Remarks by EPA - Treatment Technologies</u>, Mr. Jeffrey Kempic, US EPA Office of Ground Water and Drinking Water (9:30 - 10:45 am).

Mr. Jeffrey Kempic briefed the Committee on "Arsenic Treatment" (see Attachment F1 for his briefing notes and F2 for information provided to the panel prior to the meeting). He noted that the proposal indicates an MCLG of zero and proposes a standard of 5 ppb though EPA is also asking for comments on standards at 3 ppb, 10, ppb, and 20 ppb. Compliance is set for 3 years after a final rule is issued in 2001 for large systems and 5 years after promulgation for systems serving under 10,000 persons. **Costs and Benefits** summarized by Mr. Kempic are shown in Table 1.

Table 1. Costs and Benefits Summary

MCL	Annual CWS Cost for Treatment	Annual CWS Cost for Admin	Number of Community Water Systems	Population Served	Reduced Bladder Cancer Cases Per Year*	Reduced Bladder Cancer Deaths Per Year**
3 ppb	$639 M	$2.2 M	10,500	35.7 M	22 - 42	6 - 11
5 ppb	$374 M	$1.9 M	6,600	22.5 M	16 - 36	4 - 9
10 ppb	$160 M	$1.8 M	3,000	10.7 M	9 -21	2 - 5
20 ppb	$59 M	$1.7 M	1,200	4.4 M	4 -12	1 - 3

*Estimated benefits of avoided bladder cancer (at 20% survival rate) $90 M
Estimated benefits of avoided lung cancer $380 M.
* *Expected lung cancer deaths avoided could be 2 - 5 times as much as expected bladder cancer deaths avoided.

Mr. Kempic noted the following **Best Available Technologies** (and their maximum percent removal rates) that are identified in the arsenic proposal. These are shown in Table 2.

Table 2. Best Available Technologies

Treatment Technology	Maximum Percent Removal
Ion Exchange	95
Activated Alumina	90
Reverse Osmosis	>95
Modified Coagulation/Filtration	95
Modified Lime Softening	80

Mr. Kempic then provided summary information on the Agency's "**Major Decision Tree Branches**" of which there are 16 (see Table 3).

Table 3. Major Decision Tree Branches

SOURCE TYPE	SYSTEM SIZE*	POPULATION SERVED	PERCENT OF SYSTEMS WITH C/F IN PLACE	PERCENT OF SYSTEMS WITH LS IN PLACE
SURFACE WATER	SMALL	25-100	22	4
		100-500	53	9
		501-1,000	73	19
		1,001-3,300	76	16
		3,300-10,000	85	7
	LARGE	10,001-50,000	92	8
		50,001-100,000	85	5
		100,001-1,000,000	94	5
GROUND WATER	SMALL	25-100	2	3
		100-500	4	3
		501-1,000	2	2
		1,001-3,300	3	3
		3,300-10,000	8	3
	LARGE	10,001-50,000	4	5
		50,001-100,000	4	3
		100,001-1,000,000	5	10

*For systems serving more than 1,000,000 people, there is no decision tree. Individual analyses was done for each of

the 25 systems based on their arsenic levels. Only three systems are affected at the MCL options under consideration: Phoenix, AZ, LosAngeles, CA, and Houston, TX..

Mr. Kempic noted the following **assumptions** which are built into the decision tree analytical tool:

a) **Pre-Oxidation**: Systems with no pre-ox will add it for all technologies; chlorination is used in all cost estimates, potassium permanganate and ozone are effective as well.
b) **Coagulation/Filtration**: C/F is not likely to be installed solely for arsenic removal, systems with C/F in place will modify; assumed waste residuals will be non-hazardous
c) **Lime Softening**: LS is not likely to be installed solely for arsenic removal, systems with LS in place will modify; assumed waste residuals will be non-hazardous
d) **Activated Alumina**:

Critical Factors: Arsenic removal is pH sensitive (optimal 5.5 to 6.0); pre- and post-treatment pH adjustment necessary for optimal run length, chemical handling issues make optimal pH problematic for small systems
Small System AA: Single-column process; EBCT is 15 minutes; operate process at the natural water pH (two were selected for the analysis: pH 7 at 16,500 BVs and pH 8 at 2,900 Bvs.
Disposal Options: *Replacement Option* - media used once and then disposed at non-hazardous landfill; *Regeneration Option* - media regenerated; brine stream disposed in POTW; media eventually disposed at landfill.
Run Length-Revised Approach: Two-column approach - *roughing column* (media disposed at landfill) and *polishing column* (becomes new roughing column); EBCTs of 5 minutes per column; gives longer run lengths, greater utilization of adsorptive capacity; reduced operation/maintenance costs; smaller volume of waste needing disposal; more cost-competitive with anion exchange.

e) **Ion Exchange:**

Sulfate concentrations: Considered cost for sulfate concentrations of *25, 90* and *150 mg/L*; 150 cost was prohibitive and it was given a 0 probability in the decision tree.
Disposal: Assumed waste stream would be disposed of by 1) evaporation pond and then non-hazardous waste landfill or 2) sanitary sewer, or 3) chemical precipitation and then non-hazardous waste landfill, and brine disposed via POTW; Added corrosion control costs for all removal greater 90%.
Relation of Arsenic and Sulfate in Groundwater: This relationship is shown in Table 4

Table 4. Sulfate Level Probabilities Vs. Arsenic Influent Levels
(Based on 25 state Arsenic Database)

Influent Arsenic Level	Likelihood of Sulfate <25 mg/L	Likelihood of Sulfate 25 - 120 mg/L	Likelihood of Sulfate >120 mg/L
<10 ug/L	0.48	0.33	0.19
10-20 ug/L	0.35	0.39	0.26
>20 ug/L	0.33	0.38	0.30

f) **Reverse Osmosis:** > 95% removal efficiency; Due to cost and water loss the Agency assumed it would not be used and it is not selected in the decision tree though it is a BAT (cost estimates built on: for waste disposal by direct discharge, sanitary sewer, and chemical precipitation and non-hazardous waste landfilling, corrosion control used if > 90% removal).
g) **Coagulation Assisted Microfiltration:** Should be effective in removing arsenic but there is no full-scale operation history so it is not listed as BAT; assumed waste disposal via mechanical dewatering followed by non-hazardous waste landfill or non-mechanical dewatering followed by disposal in a non-hazardous waste landfill.
h) **Oxidation/Filtration:** Relatively inexpensive technology for small ground water systems; maximum removal assumed to be 50%; not listed as BAT because it does not have high removal efficiency; used in decision tree; assumed use only if >300 ug/L of *iron* was also present; assumed spent media disposed of at a non-hazardous waste landfill. The relationship of arsenic and iron (USGS data) are shown in Table 5.

Table 5. Relation of Iron to Arsenic Influent Levels

Influent Arsenic	Likelihood of Iron <300 ug/L	Likelihood of Iron >300 ug/L
<10 g/L	0.82	0.18
10-20g/L	0.81	0.19
>20 g/L	0.71	0.29

i) **POU/POE:** For options ion exchange/activated alumina/reverse osmosis. Assumed:
-- no POE-RO use because of water loss and waste disposal,
-- no POU/POE IX use due to potential for arsenic peaking,
– only systems in the 25-100 and 101-500 sizes would use this,
– relatively small percentage of systems would opt for POU/POE
– breakpoint between central treatment and POU appears to be around 72 households or 180 people
POU/POE Requirements: units owned, controlled, and maintained by the PWS or a person under their contract; units equipped with mechanical warnings to notify customers of operational problems, and units must meet independent certification of ANSI standards.

Mr. Kempic then discussed the four Treatment Trains that are included in the Agency analysis. These are shown in Table 6.

Mr. Kempic discussed the implications of residuals associated with arsenic. The primary assumption is that all such residuals will be non-hazardous wastes. Members noted the importance of this assumption to the Agency's cost analysis. With respect to residuals, a number of things are relevant.

One is the basis for waste classification. The **Toxicity Characteristic (TC)** is a regulatory level for designating a waste as hazardous under the Resource Conservation and Recovery Act (RCRA). The method by which a waste is evaluated to determine if it exceeds the TC is the **Toxicity Characteristic Leaching Procedure (TCLP)**. The TCLP is performed by placing residuals in an acetic acid solution with a resulting pH less than 5. The solution is rotated for 18 hours and then the solution is filtered and the filtrate analyzed for arsenic. A modification of this approach is used in California, the **Waste Extraction Test (WET)**. This procedure uses citric acid instead of acetic acid. A **Dilution/Attenuation Factor (DAF)** is used to model the change in concentration of leachate from the bottom of the landfill to the drinking water well (crude assumption is a 100X factor).

Mr. Kempic noted that arsenic treatment technologies produce 3 types of wastes: brines, sludges, and solids. The TC can apply to all three. The current TC for arsenic is 5 mg/L (100X the current MCL of 0.05 mg/L). Mr. Kempic stated that the TC may or may not change when the MCL is revised. The types of residuals considered in the Agency analysis are shown in Table 7.

Mr. Kempic stated that comments from the EPA Office of Solid Waste note that there is "No possibility that OSW would revise the As (or any other contaminant) TC regulatory levels using a uniform 100x ration." They state that groundwater fate and transport modeling has changed dramatically since the TC metals values were established and they are not set in stone. "DAFs may be higher or lower than 100x - depends on time horizon used, distance between landfill and well assumed, etc."

Table 6. Treatment Technology Trains.

TT Train Number	Treatment Technology Train 1 of 4	Treatment Technology Train 2 of 4	Treatment Technology Train 3 of 4	Treatment Technology Train 4 of 4
1	Regionalization			
2	Alternate source			
3	Add pre-ox* and modify in-place LS			
4	Add pre-ox* and modify in-place CF			
5		Add pre-ox*, add IX, POTW, and corrosion control (if >90% removal required). Sulfate 25 mg/L		
6		Same as 5, but sulfate at 90 mg/L**		
7		Same as 5, but using evaporation pond/non-haz landfill for disposal.		
8		Same as 7, but sulfate at 90 mg/L		
9			Add pre-ox*, add AA, non-haz landfill for spent media, pH at 7	
10				Add pre-ox*, RO, direct discharge, and corrosion control (if>90 removal required).
11				Same as 10, but use POTW
12				Same as 10 but use chemical precipitation and non-haz landfill
13				Add pre-ox*, CMF and mechanical dewatering/non-haz landfill.
14				Same as 13, but use non-mechanical dewatering
15			Add pre-ox*, add Greensand and POTW for backwash stream	
16		Same as 5, but use chemical precipitation and non-haz landfill		
17		Same as 16, but sulfate at 90 mg/L		
18			Same as ? but with regeneration, add POTW disposal for waste stream	
19			Add pre-ox* and POE AA	
20			Add pre-ox* and POU RO	
21			Add pre-ox* and POU AA	

*If not in place

Table 7. Types of Residuals Produced by Arsenic Treatment Technologies Considered

Treatment Technology	Sludge	Brine	Solids	Waste Disposal Options Considered in EPA Analysis
Ion Exchange		X		*Brine*: POTW waste disposal, evaporation pond; direct discharge; chemical precipitation
Activated Alumina		X	X	*Brine*: POTW waste disposal, evaporation pond; direct discharge; chemical precipitation *Solids*: non-haz landfill
Reverse Osmosis		X		*Brine*: POTW waste disposal, evaporation pond; direct discharge; chemical precipitation
Coagulation Assisted Micro-filtration	X			*Sludge*: non-haz landfill, mechanical dewatering, non-mechanical dewatering.
Greensand			X	*Solids*: non-haz landfill
Modify Coagulation-Filtration	X			Sludge: non-haz landfill, mechanical dewatering, non-mechanical dewatering.
Modify Lime Softening	X			Sludge: non-haz landfill, mechanical dewatering, non-mechanical dewatering.
POU/POE Activated Alumina			X	*Solids*: non-haz landfill

Mr. Kempic discussed a series of case studies that have been conducted since 1992 that consider arsenic residuals. He concluded that:

- Residuals from LS, IX, AA, RO, CMF, Iron removal, and POU/POE AA...should be non-hazardous] (almost all TCLP results wold pass even a TC lowered to 0.5 mg/L),
- For CF, only 1 plant studies showed that it may not pass a lowered TC of 0.5 mg/L. It would, however, pass the current TC of 5 mg/L. The other 6 studies would pass even a lowered TC of 0.5 (the California WET test may be an issue for CF - of 3 plants studied, 2 plants wold not pass the current TC and 1 would pass th current TC,
- POU/POE AA residuals should be non-hazardous (Simulations suggest residuals would be hazardous in only extreme worst case scenarios),
- Iron Oxide Coated Sand may be a concern (technology is not in the decision tree)
- Potential restrictions on AX brine disposal:
  - Technically Based Local Limits (TBLLs) for the POTW could be based on: arsenic in POTW biosolids, arsenic in discharge from POTW, and total dissolved solids (TDS) increase from salt.
  - Sulfate will dictate waste generation - frequency and salt use.
  - TBLLs based on Arsenic take into account the background arsenic level in the municipal wastewater (now based on drinking water quality untreated), the

background level will change due to treatment of drinking water,

- TBLLs would likely need to be revised since background level has been lowered and the revised TBLL would be used to determine if the brine stream could be discharged to POTWs.

DWC Panelists noted concern with the EPA background material provided on its Treatment Technology analysis. They noted that the decision tree that they were asked to comment upon has not been provided to the panel. The only thing provided is a brief description contained in the written material and the summation from Mr. Kempic's presentation (Dr. Hering and others), that the cost-benefit information is not clearly described (Dr. Evans), and that no sensitivity analysis was provided to allow the panelists to determine the factors that drive the Agency's analysis. The model output is given in brief, but information on what happens within the model is difficult to discern (DeBaun).

Break (10:45 - 11:00 am)

3. <u>Public Comment</u>: (11:05 - 11:20 am)

a) <u>American Water Works Association</u>: Dr. Alan Roberson, Director of Regulatory Affairs, American Water Works Association, provided a comment for consideration of the DWC members (see Attachment G–note included within this attachment is the information provided by Dr. Roberson during the DWC meeting of March 14, 2000-- also see that portion of the March 2000 minutes that focused upon arsenic - Attachment H). Dr. Roberson primarily directed his comments toward treatment costs, Benefit-Cost analysis, and the proposed Health Advisory. His comments made at the March DWC meeting covered most of the AWWA issues on the arsenic health effects data.

Dr. Roberson noted that "The current EPA cost estimates for the arsenic proposal fall well outside of the expected range of national compliance costs as compared to the independent estimates and EPA's prior estimates, and this difference is not readily explainable." He noted that more detailed information on the EPA analysis is needed to see where the differences come from. Possible overlooked cost elements include:

- o Land acquisition costs. A large percentage of groundwater systems now have no treatment infrastructure and land will be needed to permit arsenic treatment facilities to be established.
- o Labor may not be readily available in affected groundwater system and resources to provide needed training may be unabailable.
- o Production and Handling of Hazardous Wastes. The EPA analysis assumes residuals will be non-hazardous wastes. The possibility that some will be hazardous should be considered in the analysis.

Dr. Roberson noted other issues to consider including: drinking water chemical purity associated with iron-based coagulants, operator training and changes in utility management, and availability of treatment technologies for national application. As for the Benefit-Cost Analysis, Dr. Roberson noted that affordability is becoming an issue in drinking water standards. The marginal dollar taken from household income is significant. The EPA BCA misses this element by focusing on implementation dollar costs only. A "regrets analysis" (equivalent to a marginal net benefits analysis–focuses on minimizing the

total social cost of a regulation) conducted by AWWA noted that the 50 ppb standard has the "least regret" at the low end of the estimated benefits while a 10 ppb level has the "least regret" at the high end of the EPA benefit estimate while using the AWWARF cost estimates the 50 ppb standard has the highest regret at the low end of the benefit estimate and 20 ppb standard has the "least regret" at the high end of the estimated benefits.

Regarding the proposed Health Advisory, Dr. Roberson noted that a level of concern in such an advisory, if published before a final regulation, could become the defacto MCL. Because of EPA's admitted lack of understanding of health effects of arsenic in US populations, AWWA thinks that such an advisory would be premature and only confuse the issue. They also recommend more interaction with the medical/pediatric community on the need for an advisory.

4. Discussion of EPA's Arsenic Proposal: Treatment Technology and Cost Issues
DWC and EPA representatives: (11:20 am - 12:30 pm)

The Agency asked the DWC to respond to two charge questions relevant to treatment technologies. One focused on EPA's analysis of how residuals from arsenic treatment might be handled. Specifically it asked: "Based upon a review of the submitted materials, does the SAB believe that the EPA produced an accurate projection of the likely disposal options for arsenic residuals and the distribution of these options by treatment type? What are the SAB's views on the advantages and the limitations of the various waste disposal options? What effect, if any, would the SAB's analysis of these advantages and limitations have on the probabilities assigned? What are the SAB's views on which options will be more likely used by small systems (less than 10,000 people), and which will be more likely used by larger ones?"

The second question focused on the decision tree itself. It asked: *"Does the SAB agree with the principal "branches" of EPA's decision tree described in the submitted documents and the likelihood that these options will be used for systems of various sizes with various source water characteristics? What views does the SAB have on EPA's description of the advantages and limitations of these treatment technologies? Would the SAB's views on the these advantages and limitations affect the probabilities assigned?"*

The discussion of these questions was handled as a whole. The lead discussant was Dr. McMullen. First, Dr. Bull asked members to note any general issues they wanted to raise with either EPA or AWWA. Members enquired about the regrets analysis, purity of treatment additives, the health advisory, the need to consider risks associated with added truck traffic in areas surrounding treatment facilities who would need to treat for arsenic, the need to consider whether small system operators would "walk away" from their facilities because of their possible nonprofitability if treating for low levels of arsenic and the follow on problem of users reverting to their own wells that would have no treatment thus increasing all types of risks, and the difficulty in comparing the EPA analysis with the AWWARF analysis of cost because of the lack of information provided to the DWC by EPA - specifically the actual decision tree EPA used and possibly the EPA Regulatory Impact Analysis.

At this point, Dr. McMullen led the discussion of the treatment technology issues. The primary concern he noted was the Committee's difficulty in determining the content and process involved in the decision tree. Though some elements of the tree are discussed in the background and in the Agency

presentation earlier in the day, the key parameters in the model are not clear nor is the manner in which the models operate. In essence, the Committee is somewhat flying in the dark in that regard. Dr. DeBaun noted that the full tree might not be necessary. Rather, he thought details on how key parameters operate in the model might suffice. Others suggested that without additional information, it was not possible to know the decision rules that would cause one to go down one branch of the tree versus another.

Mr. Kempic noted that he had, with him today, one copy of the full decision tree. (NOTE: This copy was never provided to the Committee. The Committee assumed that this was because the actual proposal had not been formally published and therefore significant amounts of the background material were embargoed until that time).

Members then discussed the feasibility of going from a 50 ug/L level now to 5 ug/L in a 3 year period. Many places do nothing at this point. To get to a level of 5 ug/L in one step, especially in an area where the highest level of expertise may be the high school chemistry teacher could be very difficult. The cost implications shown in both the EPA and the AWWARF estimates are all paper exercises and have no real experience as a basis. The real cost is uncertain, especially because many cost elements are not available.

Members also noted potential problems with discharges directly to sanitary sewers that is projected for ion exchange. TDS considerations alone may make sanitary sewer discharge invalid for any place in the Southwest.

Members noted possible problems with the TCLP determination of real world situations. Landfill pH can be from 8 - 9 and results from the TCLP may not be valid for what can actually happen there in regard to arsenic leaching.

Lunch (12:45 - 1:45 pm)

Continuation of Discussion on Treatment Technolgy Issues

Members noted in regard to the 2.5% affordability criterion for households, that other standards are in the process of being evaluated and that they also need to be considered against the margin that is available to cover additional treatment to reach a variety of new standards.

At this point, Dr. McMullen summarized the comments he had hear regarding the two technology/cost charge questions:

1) It is difficult to be totally responsive to the questions without access to details on the decision tree.

2) Several things are assumed in the decision tree may be of difficulty in implementation:
   a) discharge to sanitary sewers
   b) assumption that residuals are all non-hazardous (particularly in California)

3) Proximity of the MCL to the PQL and the affordability determination

4) Multi versus single units in small systems

5) The branches in the decision tree are only generally known to us not specifically.

6) General comfort with efficiency off treatment technologies discussed

7) Pilot/lab level treatment information versus full scale results give reliability concerns. There are usually surprises when one gets to full scale real world applications.

8) Corosion of treatment plant materials

9) How well the TCLP predicts landfill behavior when focus on arsenic

10) Cost of uncertainties at different MCLs (is uncertainty level consistent across alternative MCLs? Even if so, the cost of uncertainty across different system sizes is consistent.)

11) Impact of treatment technology on fluoride concentration in drinking water is not considered–in some cases arsenic treatment may remove natural fluoride and it may need to be reintroduced for dental health purposes.

5. Consideration of SAB Executive Committee Request on Residual Risk (3:30 to 4:15 pm)

Dr. Bull briefed the committee on the SAB EC's request to the standing committees. The EC concern came from their consideration of the CAA requirement to evaluate residual risk from hazardous air pollutants. As the review report was discussed in the EC, members noted the difficulty in completing the Congressional mandate, that is, they wondered if a doable task had been placed in front of the agency given the large number of risk scenarios that must be assessed, the resource available to EPA, and the incomplete nature of the underlying science information. This was generalized to a question of possible disconnects between science assessors and decision makers at a number of levels: 1) Congress to EPA, 2) EPA decision makers to agency risk assessors, and 3) EPA program managers to SAB reviewers. In essence, the request is for examples where their appears to have been a disconnect between policy makers and scientists in what was desired by decision makers versus what was delivered by scientists. The intent is to look at a number of cases and to see if solutions can be found to bring needs and deliverables into alignment. The arsenic review may be the DWC example elevated to the EC.

6. Scoping of Day 2 Activities (4:15 - 5:35 pm)

Dr. Bull noted the order in which he wanted to discuss the three health charge questions on day two. He then asked panelists if there were issues to resolve now that would make the day 2 discussions more effective. The issue of sensitive populations, especially children, will be important in the discussions tomorrow. One point will be how different children are from adults, the strength of the Taiwanese and Utah epidemiology studies, the influence of speciation in risks, research, dose-response range for non-cancer endpoints compared to carcinogenicity, the status of additional analysis of the Utah epidemiology data, and the influence of models selected on how dietary exposures impact arsenic risk estimates.

B. Tuesday, June 6, 2000

1. Reconvene the Meeting (8:05 am)

Dr. Bull reconvened the meeting and introduced Dr. Louise Ryan who made her voluntary disclosure.

2. Opening Remarks by the Agency - Health Effects (8L15-9:20 am)

a) Overview (Ms. Irene Dooley)

Ms. Dooley noted that there are approximately 55,000 Community Water systems (CWS) in the U.S. Of these, about 44,000 use ground water sources and about 11,000 use surface water. About 91% of these systems serve 10,000 or fewer persons. Nearly 150 M persons are served by systems of greater than 10,000 in size. There are in addition approximately 20,000 Non-transient Non-Community Systems (nearly 19,000 use ground water sources). Only CWSs with greater than 25 full time residents are subject to the arsenic rule (see Attachments I1 for her briefing notes and I2 for the information provided to the DWC for review prior to the meeting). The distribution of arsenic in U.S. source waters is based upon compliance data available from 25 states. A summary of this information is contained in Table 8.

Ms. Dooley noted that the proposed arsenic regulation includes an MCLG of 0 and a standard of 5 ppb. In addition, the Agency is asking for comments on the MCLs of 3, 10, and 20 ppb. Compliance is projected for 2004 for CWS serving over 10,000 persons and 2006 for those serving fewer (assuming a promulgation date of 2001). NTNCWS will be required to monitor and report to the public three years after promulgation; however, they will not be required to treat.

Members noted the following in response to Ms. Dooley's presentation:

i) Decision Logic: Panelists noted that it was difficult to follow EPA's decision logic from the background information provided to the DWC by EPA. It is not clear why the EPA and AWWARF cost estimates differ by a factor of 5. Information on precision of EPA's estimates would be helpful. Agency representatives noted that EPA numbers focused on least cost technologies, focused on small systems, and made different assumptions about residuals management than AWWARF. They also noted that precision information is available for the EPA estimates.

ii) Risk: Panelists asked why EPA based its estimate on the Taiwan data and not the data from the Utah study; the influence of smoking in the comparison populations; and noted the need for better exposure data to help interpret the epidemiology studies. Further, additional consideration of the Taiwan study from the perspective of narrower comparison populations could influence the risk estimates derived for the proposal by EPA from that study. EPA representatives noted that both sets of data could be used, but that certain factors in the Utah study are currently being reevaluated and are not yet available to the Office of Water. They also suggested that work done after the original Taiwan study provide better information on exposures.

iii) Benefits: The panelists noted that benefits would be larger if skin cancer and other endpoints were included in the estimates. EPA representatives noted that these are handled qualitatively in the proposal.

Table 8. Arsenic Concentrations by NAOS Region

NAOS Region	States with Compliance Data in the Region	Region Name	Arsenic Concentrations (GW/SW*)		
			Percent >5 ppb	Percent > 10 ppb	Percent > 20 ppb
1	ME, NH, NJ	New England	21.0 / 9.0	7.0 / 1.0	3.0 / 0.4
2	KY, NC	Mid-Atlantic	0.0 / 0.1	1.0 / 0.1	0.1 / 0.001
3	AL	Southeast	0.5 / 0.03	0.2 / 0.001	0.1 / 0.0
4	MN, MI, IL, IN, OH	Midwest-Central	15.0 / 1.0	6.0 / 0.4	2.0 / 0.1
5	KS, MO, NM, TX, OK, AR	South Central	10.0 / 1.0	4.0 / 0.3	1.0 / 0.1
6	MT, ND	North Central	13.0 / 4.0	6.0 / 0.8	2.0 / 0.1
7	OR, CA, NV, UT, AZ, AK	West	25.0 / 7.0	12.0 / 3.0	5.0 / 1.0

*GW = Ground Water; SW = Surface Water

b) Costs and Benefits (Dr. John Bennett)

Mr. Bennett recapped the costs noted earlier (see Table 1). A 5 ppb standard would have annual treatment costs of about $374 million and would impact some 6,600 CWS that serve almost 22.5 million persons. Benefits (reduced bladder cancer cases and death) are also shown in Table 1. A 5 ppb standard would result in an estimated 16 to 36 fewer cancer cases and 4 to 9 fewer deaths per year. EPA estimated a $90 million annual benefit from this reduction. They also suggested that lung cancer deaths avoided could be from 2 to 5 times the bladder cancer levels (best estimate $380 million). EPA's summary of costs and benefits is shown in Table 9 (also see Attachment I).

Table 9. Estimated Costs and Benefits of Alternative Arsenic MCLs ($Million, 1999)*

MCL	90^{th} P Risk	Total Costs		Total Benefits (Bladder Cancer**)		Total Benefits (Lung Cancer)	
		Annualized at 3%	Annualized at 7%	3%	7%	3%	7%
3 ppb	4 to 6 x 10^{-5}	$645 M	$756 M	$44 M	$104 M	$47 M	$450 M
5 ppb	6 to 11 x 10^{-5}	$380 M	$445 M	$32 M	$ 90 M	$35 M	$380M
10 ppb	1 to 1.7 x 10^{-4}	$165 M	$195 M	$18 M	$ 50 M	$20 M	$224 M
20 ppb	1.4 to 2.4 x 10^{-4}	$ 63 M	$ 77 M	$ 8 M	$ 30 M	$ 9 M	#130 M

*Potential nonquantifiable health benefits: Cancers: skin, kidney, nasal, liver, prostate and other diseases: cardiovascular, pulmonary, immunological, neurological, endocrine, reproductive/developmental.

**Upper bound estimates assumes 80% mortality in Taiwan data

***Range assumes risk of fatal lung cancer is 2 to 5 times risk of fatal bladder cancer and 80% mortality.

c) Source Contribution and Inorganic vs. Organic Arsenic (Ms. Irene Dooley)

Ms. Dooley noted that the proposed standard is in terms of total arsenic. Tests are available for determination of total arsenic at a cost of from $15 - $50 per analysis. There is no EPA-approved test for inorganic arsenic alone in drinking water (the predominant form therein). She noted that wells in the Taiwanese study had < 1 ug/L methylarsonic acid. Some California samples contain > 1 ug/L DMA/MMA. As for food, according to the NRC report US food contributes from 10 - 12 ug/day inorganic arsenic. At an MCL of 5 ppb, drinking water and food would contribute about the same amount of arsenic to individuals each day. She noted that the Taiwanese food may contribute 50 ug/day by comparison.

d) Health Effects Charge (Dr. Rita Schoeny)

Dr. Schoeny summarized the three health charge elements for the Committee (See Attachment I). Health question 1 addresses inorganic arsenic as the principal form of arsenic causing health effects. EPA asks if the SAB has perspectives on his that EPA should consider in its risk assessment. They also ask if organic arsenic contribution to risk is significant.

Health question 2 addresses the implications of natural arsenic exposure through food. EPA asks if the SAB agrees with the NRC that food contributions should be considered in setting a standard, and if so, how to consider it and communicate this to the public. Dr. Schoeny noted that EPA cannot eliminate the food exposure and that EPA's risk assessment focused on incremental risk from drinking water not food. EPA asks if it should evaluate arsenic in drinking water in comparison to that in food.

Health question 3 addresses potential sensitivities of children. EPA asks if precautionary advice on using "low-arsenic water" i preparing infant formula is appropriate given available information. This advice would be used during the period between rule promulgation (2001) and implementation (2004 or 2006). EPA's rationale for the concern includes a recognition that vascular and brain development are ongoing in infants and that brain development continues into young adulthood. Further, cerebral strokes are not uncommon in children and their causes are unknown.

3. Public Comments on Health Effects and Risk Issues (9:20 -9:30 am)

a) EPRI (Dr. Kenny Crump)

Dr. Crump discussed a bench mark analysis for arsenic which derived Benchmark $Dose_{10}$ (BMD_{10}, i.e., the water concentration corresponding to a 10% additional risk from lifetime exposure to inorganic arsenic from drinking water) for a number of cancer and non-cancer endpoints (See Attachments J1 and J2). Studies of non-cancer effects addressed endpoints such as ischemic hart disease, cerebrovascular disease, diabetes mellitus, blackfoot disease, hypertension, etc. Carcinogenic endpoints addressed the lung, bladder, kidney, liver, and uterus. BMD_{10} for non-cancer effects were quite comparable to those for carcinogenic effects.

In response to earlier comments on the Utah epidemiology study, Dr. Crump noted that he had

recently reviewed a reanalysis of data for this study which used internal comparison groups instead of broader ones. The results should be provided to EPA soon.

b) Other Public Comments

Mr. Miller, DFO for the Committee noted that comments had also been received for entry into the record from Richard Wilson, Harvard University (addresses the linearity/threshold issue--Attachment K) and Jeffrey W. Stuck, Safe Drinking Water Program (states of Arizona, Nevada, and New Mexico plus University of Arizona–see Attachment L–addresses speciation vs toxicity, other considerations for Taiwan, decision tree, food exposure). Mr. Miller also reminded of the public comments and written submission of Dr. David Cragin, Environmental Arsenic Council, from the March 2000 DWC meeting (see Attachment M) and those from Dr. Roberson of the AWWA from the same meeting (see Attachment H).

Break (until 10:20 am)

4. Panel Discussion of the Health Issues Associated with Arsenic (Initiated during Dr. Schoeny's presentation and continued after the break until 10:40)

a) General Comments

General comments made by individual DWC Panelists included:

1) veterinary supplements for poultry and beef contain arsenic,
2) the definition of "low arsenic water" is not clear,
3) children are a special population, they are not small adults,
4) non-cancer effect based MCLs might lead one to an MCL close to one derived from cancer,
5) lack of clear data on non-cancer effects in children may result in people ignoring a health advisory even if EPA issues one–it may be a good idea to actually look at childhood components of existing epidemiology studies to see if that adds important information,
6) EPA's drinking water ingestion report notes high water intake per unit body weight for infants,
7) High proportions of bottled water come from CWS taps in some parts of the U.S.
8) Arsenic in home grown crops may come from irrigation with drinking water containing arsenic,
9) Methylation may accelerate excretion of arsenic, but it may not be as clear that it is detoxifying, it may be generating a toxic intermediate,
10) How is lung cancer used in the decision process,
11) The manner in which drinking water intake was used in the risk analysis was questioned; the variability in intake estimates may be the major source of variation in the risk analysis.

b) Panel Conclusions on Potential Sensitivities of Children

The panel had a wide ranging discussion of the proposed advisory with EPA and within itself. Many pros and cons were suggested for an advisory. During the discussion, Dr. Evans proposed what he suggested might be some minimal sample language that the panel could consider as advice on such a statement. The statement noted arsenic's carcinogenicity, the suggestions of cardiovascular effects from arsenic exposure, the impending EPA drinking water regulation, the transitional nature of the advisory for

the period prior to implementation, the increased drinking water intake (body weight basis) of children, the uncertainty of the risks involved, the potential for parents to respond to the issue by considering alternative water sources, and the advisability of seeking advice on individual actions from medical professionals. The panel members each noted their concerns and agreements with the statement as they discussed whether it would be acceptable. In summarizing the panel's conclusion on the need for an advisory, Dr. Bull noted that the Committee was clearly of two minds – that is, some supported an advisory and some did not. The panel's split on the need for an advisory will be noted in the report section which Dr. Davis will draft. The response will note the split in the panel, that it is up to the agency to decide on the need, and if EPA decides to go forward with an advisory, it should consider, and or plan for, a number of issues prior to issuance of the advisory including:

i) Underlying Science:

- Whether or not an advisory is issued is a policy call not a science call; the SAB focuses on science itself which in this case is hard to see clearly.

- The lack of clear health data indicating children are at greater risk for arsenic is a concern. While children were certainly at risk in the studies cited, the outcome measures were not distinguished by age at exposure.

- Two panelists reacted strongly to the assertion of no data supporting the need for a health advisory. They feel there is sufficient data on to do so.

ii) Content of an Advisory:

- The language in a health advisory will be important if EPA goes forward; the intended audience must be considered; language that will speak to medical professionals may not be meaningful for lay persons who you want to follow the advice.

- The language should inform not alarm.

- Misdirected actions may occur when one tries to address arsenic risk from this source that result in increasing other risks (e.g., decreasing fluid intake to the child or shifting to other beverages such as bottled water whose arsenic content is not known as a result of the advisory).

iii) Support for Those Receiving Advisory:

- There needs to be a resource in place to help lay persons interpret the advice in an advisory; the pediatric medicine community was suggested as a resource to help in this regard.

- Establishing the 'infrastructure' needed to respond to such an advisory is not a trivial matter.

iv) Need for Advisory:

- o An advisory might be more necessary if the promulgated MCL is on the high end of the agency's alternatives (10 or 20 ppb) than if on the low end (3 or 5 ppb).

- o Issuance of an advisory requires hard quantitative data on the risk and conversely for some, issuance of an advisory can be justified even if hard quantitative data do not exist.

- o Do current consumer confidence reporting requirements duplicate the intent of an advisory?

v) Risk Implications:

- o Irrational decisions may ensue when one tries to address arsenic risk and increase other risks (e.g., decreasing ones total water intake by shifting to other beverages because of the advisory).

- o Shifting to bottled water may not get you "low-arsenic" water.

c) Inorganic arsenic as principal form causing health effects

Dr. Louise Ryan addressed this question via a broad view based on modeling considerations. Dr. Ryan first addressed the issue of why the Taiwanese data were chosen for modeling by the NRC. Essentially this was the only data set in which gradations of exposure could be established. Data from South America and India simply did provide this information. The NRC was simply attempting to find data to illustrate how a risk assessment might be conducted and for models to be applied, this is an essential element of developing a model.

Dr. Ryan provided the Committee with an overview of how alternative models dealt with the data. The super linear and linear models both fit the data. However, the linear model fit the data best and provided the most reasonable answers (other models discussed were log models, square root models, factor models, and an average model).

Dr. Ryan also reviewed for the committee analyses by Morales et al. (2000) that were done subsequent to the modeling performed by the NRC. The critical data are included in Table 10. The first point to be made from these analyses are the large differences in model prediction of the ED01 and LED01 values depending upon whether a comparison population was included in the analysis. If the whole of Taiwan or even the Southwestern region of Taiwan was used as a comparison group, the values differed by an order of magnitude from an internal analysis of the study area alone. Such a large difference suggests that the population studied differs in other ways from the rest of Taiwan. This could be a result of documented nutritional and socioeconomic status in this region (e.g. selenium deficiency, probable decreased methyl donors in the diet, elevated arsenic in food, rural population) that gives rise to a cancer mortality rate independent of arsenic in drinking water that is greater than the remainder of Taiwan.

Table 10. ED01 (LED01) Comparisons of Bladder and Lung Cancer from Taiwan Study

	Bladder Cancer		Lung Cancer	
	Male	Female	Male	Female
No Comparison	395	252	364	258
	(326)	(211)	(294)	(213)
Taiwan Comparison	22	21	11	8
	(10)	(17)	(8)	(6)
SW Taiwan Comparison	21	19	10	10
	(17)	(16)	(8)	(8)

Table 10 also clarifies the point made by the NRC when they noted that the lung cancer mortality could be 2-5 times greater than bladder cancer. As can be seen in the Table, when the lung cancer rates are calculated as an increment attributable to drinking water arsenic they are essentially the same as that seen for bladder cancer.

With respect to the Utah study, Dr. Ryan noted that it is difficult to use that data in a quantitative way for reasons similar to the difficulties encountered with the Taiwanese data. It is not clear that the comparison population chosen was appropriate. Moreover, subjects exposure was characterized by ppb-years, confounding the association of exposure with age. These two variables cannot be dissected out of the data that was reported.

d) Carcinogenic and Non-cancer Effects and the Forms of Arsenic

Dr. Dragan discussed the assertion in the charge that inorganic arsenic is the principal form causing toxicity. She noted that arsenic is accepted as a human carcinogen through the inhalation route and is a human carcinogen through the oral route following high dose exposures. The mechanistic data supports non-linear modes of action, the practice in risk assessment would indicate that a known human carcinogen be treated in a linear fashion. The choice as to which way to treat the data is one of policy. The science (animal and in vitro mechanistic) support non-linearity in the dose response curve for healthy populations exposed to lower levels than found in the blackfoot region of Taiwan. Policy indicates a linear analysis based on the demonstrated human carcinogenicity of arsenic at high dose. Given the default linear policy, the use of all of the epidemiological data and an accounting for confounders is essential (i.e., the U.S. bladder cancer data in Utah must be used to establish a baseline and the various confounding problems in Taiwan need to be considered in the analyses as discussed by Dr. Bull and Dr. DeBaun). As stated by Dr. DeBaun, the SEER data on cancer incidence in the US and the USGS or other measures of US arsenic exposure should be considered.

Further, arsenate and arsenite do not appear to be complete carcinogens in health (non-human) animals fed nutritionally complete diets. The exception is that DMA is an animal (rat) carcinogen at very high dose (the dose response is highly non-linear). Studies in various tissues indicate a promoting effect of the arsenic metabolites that have been examined.

Dr. Harper noted the abstracts she compiled for many studies that address arsenic and non-cancer effects (see Attachment O also see the list of additional studies located by the Committee as it prepared for the meeting in Attachment P). Many things are going on that suggest a variety of enzyme changes involved. Little concrete though to quantify. A total arsenic approach makes sense in this regard. Dr. Harper and Dr. Dragan will prepare a written description of their concerns. They should discuss the speciation issue.

e) Dietary Contribution and Arsenic Risk

Dr. Baker discussed his evaluation of the implications of natural arsenic exposure through food. He first summarized the background information on the primary form in drinking water, the types in foods, the average daily dietary intake, variations in food (individuals, regional, and levels in food itself), and the proportion in water vs. food at alternative arsenic MCLs. He noted again that if we are focused on a linear extrapolation model and if we are looking at incremental risk, the dietary component does not affect the increment, that is, it's a constant in food regardless of the MCL we consider. He also noted that if this were a Food Quality and Protection Act issue, we would be adding both together (food and drinking water), but here we are only concerned with the drinking water increment. Given this, there is not much the agency can do to consider the food level in setting an MCL.

Panel members noted that it makes some uncomfortable to ignore the food increment; that if one thinks of arsenic in the way that radon was considered in drinking water, i.e., higher levels in drinking water can be offset by addressing levels in indoor air; that regardless, if you decrease arsenic in drinking water you still reduce risk even if you can't address food levels; and some would lower arsenic in drinking water as much as possible just because it can't be addressed in food.

f) Proposed MCL

One member asked if the committee should be commenting on the proposed 5 ug/L MCL? He noted that the benefits of reduced health risk suggest about$600 M in benefits while cost data suggest about $300 M. The Committee can address the technical components of the benefit and cost estimates and note whether it feels that flaws in the technical analysis bias the benefits and costs that have been identified. However, the selection of an MCL is a policy call and not so much the Committee's domain. It appears that the main criteria for the MCL are from the health side and then feasibility comes to play.

Panelists discussed the difficulty for some systems in getting to the 5 ug/L level in one increment of change. Given that large systems may be doing nothing at this point, and because the technologies may not all be fully field proven, a tiered approach of a higher level (e.g., 20 ug/L) could be used as a first step with an ultimate target at a lower level (e.g., 5 ug/L). The ability to move further could then be addressed during the time for the cyclical review of the standard. Some may chose to go directly to the lower MCL regardless of the tiered approach because of the power of public opinion in drinking water issues. A standard published with a phased time schedule for arriving at the level might be better.

Mr. Taft noted that the Administrator has discretion to move off the feasible level for good reason and if the overall risk is not increased by doing so [SDWA 1412(b)(6)]. Cost-effectiveness issues will not help in this regard. He thinks that it would be difficult to build a health rationale for a level at for example 20 ug/L given the health data we have. A 20 level would be far outside the criterion of non-increased risk

that the Act requires in exercising the discretionary authority to move off the feasible level. Some panel members noted their discomfort with suggesting a higher level.

The meeting was adjourned for the day at 5:00 pm.

Wednesday, June 7, 2000*

Day three's meeting was held at US EPA's Ariel Rios Building, Room 6013, 1200 Pennsylvania Ave, NW, Washington, DC 20004, (202) 564-4533

1. Reconvene the Meeting

Dr. Bull reconvened the meeting at 8:44 a.m. and asked Dr.McMullen to begin the debrief for the Agency on the results of the review to this point.

2. Committee's Debrief for EPA (8:00 - 10:00 am)

a) Engineering, Treatment, and Cost

Dr. McMullen Summarized the notes prepared by the Engineering contingent of the panel on the treatment technology charge questions from the Agency (see Attachment Q). In regard to Disposal issues, Dr. McMullen noted that: 1) EPA has covered the spectrum of residuals disposal alternatives. However, for some alternatives, the Committee questions the viability of their use. Direct disposal to water bodies or a Publicly Owned Treatment Works (POTW) will not likely work for most systems because of problems with TDS and dilution of organic wastes. Further, the Committee questions the assumption of non-hazardous classification of waste brines and sludges.

The Committee was not able to fully evaluate the EPA Decision-Tree that was used to make predictions about technologies that might be implemented by various systems in response to a lowered arsenic MCL. Information to describe the decision tree was limited to a general description of some factors considered and a small amount of the decision rationale for these factors. In regard to what the Committee was able to determine of the Agency's approach, Dr. McMullen stated that:

1) The list of Best Available Technologies seems to overstate the case–the Committee felt that none of those listed had been demonstrated in full-scale operations for arsenic removal. Some have been used at full scale, however, they have not been operated optimally for arsenic removal;
2) The list of BAT may bias technology selection by systems against more promising emerging technologies;
3) The model does not account for land acquisition costs which might be substantial when wells are located on small plots of land within developed sections of cities;
4) The cost of replacement chemicals does not seem to be included;
5) It is not clear whether monitoring costs for POU/POE systems is adequately represented;
6) It is not clear that the model includes the costs for increased training and certification of operators; and
7) Uncertainty does not appear to be clearly addressed in the discrete numbers generated by the model; a range would be more appropriate.

In addition, Dr. McMullen noted concern with the affordability criterion of 2.5% of median household income. They reminded the Agency that for those households in the lower 50% of income, the impact will be proportionally greater than those in the upper 50%. This is of heightened concern because of the large number of drinking water regulations that are now pending at the Agency which would also need to be covered by the 2.5% level. Further, Dr. McMullen noted that the basis for determining the PQL of 3 ug/L for arsenic was not clear. They questioned if it was developed in laboratory waters or natural waters. If not from natural waters, the PQL might actually be higher. For both of these issues, past DWC reports have been provided to EPA. Both will be considered in the Committee's ultimate advice in this regard.

Finally, Dr. McMullen noted that because of the high level of uncertainty in many of the factors cited by EPA in the proposed 5 ug/L MCL. This uncertainty is higher at low values of the MCL. He suggested that it is inappropriate to install the listed technologies until reliable information is available (as in the past experience with the Information Collection Rule). Dr. McMullen suggested a Committee position that the rule be implemented in a phased approach. For example, EPA should consider setting the MCL at 20 ug/L as a first step with a place holder (target) of 5 ug/L. Additional performance and cost data could be collected prior to the first 6-year review cycle for the MCL could then be used in reaching the final MCL.

Mr. Taft of EPA asked for clarification of the assumption of a near zero applicability for POTW disposal of arsenic treatment residuals. Various panelists noted that it was due to their opinion that: 1) TDS will drive whether or not this option is available; 2) this applies to ion exchange and activated alumina; 3) the affordability issues mentioned above; and 4) the opinion of some members that the actual costs may be greater than estimated by EPA (difficult to evaluate given the sparse information on EPA's decision tree).

Mr. Kempic then responded to some of the day one comments regarding the AWWARF cost assessment approach. He suggested that the flow chart provided in the AWWARF document was misunderstood by the panel and did not apply to the cost estimate as they believed when discussed earlier. No additional detail was provided on EPA's approach.

b) Health Effects

Dr. Bull then summarized the suggested Committee comments on the health effects questions raised in the Agency charge. He noted that in regard to the Agency health questions:

> i) Principal form of arsenic causing health effects: It is not clear which form is actually responsible because of uncertainties on metabolism of various forms and how that affects their toxicity. For the rule, he suggested that it is appropriate to think in terms of Total Arsenic.
>
> ii) Implications of natural arsenic in foods: Whether natural arsenic matters in the risk estimate depends on the extrapolation model that is used. The background levels can not be ignored in EPA's communications about the standard. It would be reasonable to compare arsenic to the radon case in explaining the drinking water risk increment. At high arsenic levels, drinking water arsenic is a player in

total risk; however, at very low levels, total risk would come from elsewhere.

iii) Health advisory on low-arsenic water for infant formula: The Committee did not come to consensus in support of the need for such an advisory based on information available on the issue. There are pros and cons associated with an advisory. Issues that EPA must consider include: target audiences, how information will be disseminated, and a trusted source of follow up information for those receiving the advice. [See also the comments at section 4.b)for Tuesday, June 6, 2000 in these minutes).

Dr. Bull also noted additional perspectives on the Agency charge question on the principal form of arsenic responsible for its toxicity that are based on Dr. Ryan's presentation to the panel (see Attachment R). He noted that in her characterization, the NRC did not conduct a risk assessment. It looked at the robustness of existing data for conducting risk assessments. In regard to the assertion of a 2- o 5-X factor for lung cancer versus bladder cancer, he noted that according to Dr. Ryan's work, lung cancer is more on the order of bladder cancer's level than the 5-X factor suggested by EPA. Further, internal comparison populations give better view of what the real picture is. The sharp drop in the curves coming from some models discussed by Dr. Ryan is a clue to something else that is going on in cancer development.

Dr. Bull also stated a strong support for EPA's completion of the re-analysis that was mentioned during Dr. Crump's public comments and alluded to earlier in this meeting. It could have an impact on what messages can be derived from the Utah epidemiology study and may even help you weigh what you take from the Taiwan dose-response information. It might be the case that the U.S. risk level is between that suggested by Utah and Taiwanese epidemiology.

In terms of benefits, bladder and lung are now in EPA's tables. Other effects should be reflected (e.g., the cardiovascular endpoints discussed earlier). In addition, it is not always the case that cost estimates are more certain than benefits. Costs could also be understated. Mr. Taft of EPA noted that other benefits are included in EPA's analysis in a qualitative manner.

In terms of lowering the MCL, one of the panelists noted that there is support for lowering the level from the current 50 ug/L. The equivocations noted in this meeting are about details and the final level, not the need for lowering.

Mr. Taft enquired about a Committee suggestion on the MCL at this point. Dr. Bull noted that there seems to be a feeling with some that the Agency's discretionary authority might be used to set a higher MCL. However, it is not clear where the Committee is on such a level at this point. The Committee now seems to be focused on the viability of phasing a standard itself.

In response to a suggestion that looking at the marginal cost of going from one MCL to another (e.g., going from 5 to 3 ug/L has a 50X cost implication while going from 20 to 10 ug/L has only about a 3-X impact on cost), Mr. Taft noted that the major driver was maximizing public health protection and the current projection of a risk range around 10^{-4}.

Mr. Taft noted that it wold be very helpful if the Committee could offer some concrete advice on

how EPA should take the many uncertainties into account quantitatively (e.g., how much should one adjust for the Selenium issue, etc.). One such possibility noted by Dr. Evans was to use a "Formal Expert Judgment" approach which takes a systematic approach to getting such help. A documented range of opinion is possible with such an approach. The book entitled, *Uncertainty*, Granger Morgan and Max Henrion was suggested as background reading on such approaches.

3. Planning for the August 8-9, 2000 Drinking Water Committee Meeting (10:00 - 10:30 a.m.)

Dr. Bull and Agency representatives suggested ways that the Committee might engage with the Agency on the soon to be arrived at results of the Microbial/Disinfection Byproducts 2 Stakeholder process. Dr. Bull generally characterized the nature of the stakeholder interactions to this point and suggested that health risk seems to have taken on a qualitative influence in the proceedings. It is unlikely that the DWC will offer anything to change the outcome of the interaction leading to the stage 2 proposal. He suggests that the main issue he sees is how surrogacy influences the way the problem is analyzed and the likely manner in which the proposal will be focused. He suggested one possibility would be for the DWC to look at biological plausibility issues and suggest some topics for continued research in order to get to a point where surrogates would not occupy such a commanding role in these rules. We will continue our discussion of this issue when we reconvene at our August 8-9, 2000 DWC meeting.

4. Break-Out Sessions to Draft Sections of the DWC Report on Arsenic DWC (10:30 - 12:00 noon)

Various members then dispersed to draft pieces of the report to be compiled on arsenic.

The meeting was adjourned at 12:00 noon.

I certify that these minutes are accurate to the best of my knowledge.

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Dr. Richard J. Bull
Chairman
Drinking Water Committee

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Mr. Thomas O. Miller
Designated Federal Officer
Drinking Water Committee

Attachments: (Corrected)

A	Federal Register, 65(39), Monday, February 28, 2000. Pp10493-10494
B	Agenda
C	Committee Roster
D	Disclosure Process
E	Sign-in Sheets
F	Overheads, Arsenic Treatment, Mr. Kempic
G	Public statement on arsenic-AWWA, Dr. Roberson
H	Public Comments; AWWA, March 13, 2000 DWC meeting
I	Overheads; Arsenic in Drinking Water - Health Effects, OGWDW
J1	Public presentation of K.S. Crump, for EPRI
J2	Paper, K.S. Crump.
K	Public Comments (written submission only) R. Wilson, Harvard University.
L	Public Comments (written submission only) Jeffrey Stuck, Safe Drinking Water Program
M	Public Comments from 3/13/2000 DWC meeting; David Cragin, Arsenic Research Council
N	Overheads from Dr. Louise Ryan's presentation to the DWC
O	Dr. Harpers literature abstracts.
P	Pre-meeting Literature Citations from EPA and the Committee
Q	Written Notes; DWC; Treatment Technologies
R	Written Notes; DWC; Health Issues

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